PERFORMANCE WORK STATEMENT

National Academy of Sciences (NAS)

Contract #68HERC19D0011

PR-ORD-20-01985/PR-ORD-21-01003

Task Order #68HERC21F0010

Amendment 2

I. TITLE: Assessing Causality from a Multidisciplinary Evidence Base for National Ambient Air Quality Standards

EAS SHORT TITLE: NASEM Consensus Report on Assessing Causality

II. TASK ORDER CONTRACTING OFFICER REPRESENTATIVE(S):

Task Order Contracting Officer Representative (TOCOR)	**Alternate Task Order Contracting Officer Representative (Alt. TOCOR)**
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III. PERIOD OF PERFORMANCE: October 7, 2020 to ~~April 6, 2022~~ August 31, 2022

IV. PURPOSE OF TASK ORDER

The purpose of this task order (TO) is to take stock of currently available methods and frameworks for causal inference and evaluate new advancements for integrating and evaluating scientific evidence to inform causal determinations that are a critical part of Environmental Protection Agency (EPA) reviews of the National Ambient Air Quality Standards (NAAQS). This TO will provide EPA with a consensus report including approaches evaluated, recommendations for frameworks and causal analyses for causal determinations for application in NAAQS reviews, and priority research needs.

V. BACKGROUND

The Clean Air Act requires the EPA to set National Ambient Air Quality Standards (NAAQS) to protect human health and the environment. To determine if changes are necessary, NAAQS are reviewed by EPA periodically. Integrated Science Assessments (ISAs) form the scientific foundation for NAAQS review and the policy decisions that follow. To promote consistent and transparent evidence evaluation and determination of causality (i.e., defining the cause and effect relationship), EPA developed a framework for causal determination for health (e.g., cancer, noncancer) and welfare (e.g., ecosystem, climate, visibility) effects. EPA's causal determination framework was designed to promote integration of complex evidence streams from multiple scientific disciplines (e.g., exposure science, toxicology, dosimetry, epidemiology, ecology, which involve experimental and observational sciences) to support weight-of-evidence decision-making. Since 2008, when EPA first adopted a weight-of-evidence approach to assessing causality for the

criteria air pollutants[1], numerous groups (e.g., academic, regulatory and international public health organizations) have applied similar approaches and developed innovative tools, methods and practices. Those innovations offer potential approaches and analytical capabilities for evaluating possible cause and effect relationships between pollutant exposures and health or welfare observations. This TO would provide recommendations for frameworks and causal analyses for EPA to employ in ISAs for causal determinations that inform NAAQS decisions.

VI. SCOPE OF WORK

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will consider frameworks for integrating, documenting, and evaluating scientific evidence to assess causality of health and welfare effects by air pollutants as part of National Ambient Air Quality Standards (NAAQS) reviews conducted by the Environmental Protection Agency (EPA). The committee will

- Describe and assess available methods and frameworks for inferring causality of health or welfare effects within a NAAQS review. Based on those assessments, suggest how the number and description of causality categories in the hierarchy to classify the weight of evidence for causation (i.e., causal determinations) might be refined for more effective use in EPA's Integrated Science Assessments (ISAs) that are prepared for NAAQS reviews. Indicate if those categories are necessarily mutually exclusive in making causal determinations from a body of evidence, and, if appropriate, identify methods to characterize the degree of confidence in a causal determination.
- Assess new advances for integrating and evaluating scientific evidence to inform causal determinations critical to EPA's NAAQS reviews. Suggest emerging tools and approaches that might be used in the near and longer-term to integrate and synthesize evidence across studies and scientific disciplines. In addition, consider whether those tools and approaches might be used to assess consistency among independent studies within a discipline, coherence across different lines of evidence, and evidence of biological plausibility.
- Identify additional issues concerning potential confounders (i.e., other factors associated with both the pollutant and effect) that EPA might consider when assessing causality for an individual criteria pollutant that is part of an atmospheric complex pollutant mixture.

The committee's report will describe, in the context of ISAs, the types and characteristics of evidence most useful for forming a causal determination, and whether a single framework and practices related to it for assessing causality may be applied to both health and welfare effects. The report will make recommendations related to the development and use of ISA frameworks for causal determinations and describe priority research needed to improve those frameworks in the future.

Completion of this task shall include a kick-off teleconference/webinar held in conjunction with EPA and development of a draft report including approaches evaluated, recommendations for frameworks and causal analyses for causal determinations, and priority research needs by a NASEM committee. NASEM shall coordinate informational gathering sessions during committee meetings to receive input from EPA, SMEs, and the public. The resulting report shall be subject to NASEM review procedures[3] and a consensus report shall be produced.

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[1] U.S. EPA (U.S. Environmental Protection Agency). (2008). Integrated Science Assessment for Oxides of Nitrogen – Health Criteria [EPA Report]. (EPA/600/R-08/071) Washington, DC: U.S. Environmental Protection Agency. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=194645

[2] U.S. EPA (U.S. Environmental Protection Agency). (2015). Preamble to the Integrated Science Assessments [EPA Report]. (EPA/600/R-15/067). Research Triangle Park, NC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment-RTP Division. (https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[3] https://www.nationalacademies.org/about/our-study-process

DESCRIPTION OF TASKS

Task 1 – Kick-off Teleconference/Webinar and a Project Milestone chart (Contract Level PWS Task Area 2)

NASEM shall convene a teleconference/webinar and provide a milestone chart for this TO.

Subtask 1.1 – Kick-off Teleconference/Webinar

NASEM shall convene a Kick-off Teleconference/Webinar with the TOCOR and relevant EPA staff to review the study scope, committee formation, proposed milestones and deliverables, and communication plans. This teleconference/webinar shall occur within seven (7) business days of acceptance of this task order.

Subtask 1.2 – Project Milestone Chart

NASEM shall prepare a Project Milestone Chart for the consensus study report provided to the Contract Officer (CO), Contract Level Contracting Officer Representative (CLCOR) and TOCOR within thirty (30) business days of task initiation. This Project Milestone Chart should detail the significant activities for each task/subtask and expected progression of the deliverables.

Task 1. Deliverables

Task	SubTask	Deliverable	Schedule
1	1.1	Kick-off Teleconference/Webinar	Within seven (7) business days of acceptance of this TO
1	1.2	Project Milestone Chart	Within thirty (30) business days of acceptance of this TO

Task 2 – Monthly EPA-NASEM Teleconference and Written Quarterly Progress Report (Contract Level PWS Task Area 2)

NASEM shall convene a monthly Teleconference and provide Quarterly Progress Reports for this TO.

Subtask 2.1 – Monthly EPA-NAS Teleconferences

After the Kick-off Teleconference/Webinar, NASEM shall convene monthly teleconferences with the TOCOR and relevant EPA staff to review TO progress.

Subtask 2.2 – Quarterly Progress Report

NASEM shall provide written Quarterly Progress Reports to the CO, CLCOR and TOCOR. Each Quarterly Progress Report should detail progress for the tasks/subtasks and any deviations from the Project Milestone Chart.

Task 2. Deliverables

Task	SubTask	Deliverable	Schedule
2	2.1	Teleconferences	Monthly beginning after Kick-off Teleconference/Webinar
2	2.2	Progress Reports	Quarterly

Task 3 – Establish Expert Committee (Contract Level PWS Task Area 2)

NASEM shall establish an Expert Committee of up to 20 subject matter experts (SMEs), but not fewer than 12 SMEs. NASEM shall establish the committee using their procedures on committee composition, balance, and conflict of interest (COI). Recommended areas of expertise include assessing the causal nature of relationships between environmental exposures and health or welfare effects. This may includes, for example, individuals with expertise in decision analysis, epidemiology, toxicology, biostatistics, experimental sciences, toxicokinetics, exposure-dose-response modeling, atmospheric sciences, ecology, and risk analysis. The NASEM shall provide a provisional list of Expert Committee members for public comment on the NASEM website that includes biographical sketches that indicate their area of expertise within three (3) months of acceptance of this TO.

Task 3. Deliverables

Task	SubTask	Deliverable	Schedule
3	NA	Provisional list of committee members including biographical sketches, areas of expertise	Within three (3) months of acceptance of this TO

Task 4 – Consensus Study Report on Causal Frameworks and Convene Expert Committee Meetings (Contract Level PWS Task Area 2)

NASEM shall produce a draft Consensus Study Report including approaches evaluated, recommendations for frameworks and causal analyses for causal determinations, and priority research needs. NASEM shall organize Expert Committee Meetings to discuss causal determination frameworks and analyses in order to develop their final recommendations for approach(s) to causal determination for the NAAQS program and shall include an opportunity for public comment.

SubTask 4.1 Drafting and Committee Peer-Review of Consensus Study Report

SubTask 4.1.1 The committee shall produce a Consensus Study Report including approaches evaluated, recommendations for frameworks and causal analyses for causal determinations, and priority research needs at least four (4) months prior to expiration of this TO. To produce the Report, NASEM shall coordinate informational gathering sessions during committee meetings to receive input from EPA, SMEs, and the public. Generally, these meetings are expected to be conducted via webinar, but, if necessary and feasible, NASEM shall make arrangements for transportation, lodging and logistical support for committee members, NASEM staff and presenters (if needed) for at least two (2) public information gathering sessions to be held in Research Triangle Park, NC or another location (e.g., Washington, D.C.) and other committee meetings.

SubTask 4.1.2 Written list of all meeting presenters and discussants and public commenters for meeting(s) shall be provided to the CO, CL COR, and TOCOR within five (5) business days after the conclusion of the meeting(s).

SubTask 4.2 Pre-publication Consensus Study Report on NASEM Website

Once finalized and approved by the NASEM, the Consensus Study Report shall be released as a pre-publication Adobe PDF download to the public via the NASEM website at least four (4) months prior to expiration of this TO. The TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

SubTask 4.3 Final Consensus Study Report on NASEM Website and in Print

The final edited and one hundred (100) bound versions of the Consensus Study Report shall be provided to the CO, CL COR, and TOCOR as well as be available in print and Adobe PDF download via the NASEM website prior to expiration of this TO. The TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

Task 4. Deliverables

Task	SubTask	Deliverable	Schedule
4	4.1.1	Coordinate informational gathering sessions for committee members to receive input from EPA, SMEs, and the public	At least four (4) months prior to expiration of this TO
4	4.1.2	Written list of all meeting presenters and discussants for meeting(s)	Five (5) business days after conclusion of meeting(s)
4	4.2	Prepublication Consensus Study Report	At least four (4) months prior to expiration of this TO
4	4.3	Final Consensus Study Report available on NASEM website in Adobe PDF and in print along with 100 bound versions provided to TOCOR	Prior to expiration of this TO

VII. ACCEPTANCE CRITERIA

The Contractor shall prepare high quality products and that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums and should be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, and logic flow, as well as, technical accuracy, completeness, timeliness, grammatically correct, free of typographical errors, and conformance with the specific task, charge and expertise and deliverables of this Performance Work Statement. The technical information shall be reasonable complete and presented in a logical, readable manner. Text deliverables shall be provided in Microsoft Word 2016 and Adobe Acrobat. Deliverables will be accepted upon review and approval by the TOCOR.